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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,582	06/23/2003	Haim B. Gunner	07880-121001 / UMA00-16A	8442

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,582	GUNNER ET AL.	
	Examiner	Art Unit	
	Deborah K. Ware	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *6-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/23/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.

SPECIFICATION

This application is a CIP of 10/324,240 filed December 19, 2002, which claims benefit of 60/343,513, filed December 21, 2001. Applicants' acknowledge priority at page 1, lines 1-5 of the instantly filed specification but fail to indicate that the case 10/324,240 is a CIP and to present such domestic priority claims in proper sequence. Applicants are invited to properly set forth domestic priority by correcting the sequence and type of domestic priority (i.e. CIP, etc.) at page 1, lines 1-5 of the instantly filed specification.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-5 in the reply filed on October 12, 2004, is acknowledged. Claims 6-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 12, 2004.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 23, 2004, was filed after the mailing date of the office action on March 24, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The amendment filed June 18, 2004, has been received and considered. The previous rejections have been removed except for the 102 rejections over claim 1 regarding the application of Cook et al and Schisler et al of the prior office action of March 24, 2004, at pages 2-3.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections of record - 35 USC § 102

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cook et al or Schisler et al, both cited of record.

Applicant's arguments filed June 18, 2004, have been fully considered but they are not persuasive. The argument that the claimed toxins are not disclosed is noted, however, the carrier and identical bacterial active ingredient in the range required by the instant claims are disclosed and meet the required claim limitations of what the actual compositions comprises per se. Therefore, the compositions are identical to the cited prior art compositions no matter how they are used. Further, the degradative toxin activity and antifungal activity are inherent to the disclosed bacterial composition since the bacterial agents are the same. Applicants have provided no differences between the bacterial agents or included such differences in the instant claims. Therefore, the rejections are maintained for these reasons and those of record.

The following are newly applied art rejections based in part on Applicants amendments:

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-5 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 of copending Application No. 10/324,240. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The claims are identical in that the compositions are the same composition regardless of their intended use. The compositions are not changed whether they exhibit degradative activity or antifungal activity. The same microorganism is required for both activities and the same microorganism has the same properties, although may have varied activities. Therefore, the claimed composition of the instant case and that of the copending claims of the other case are identical.

Furthermore, since claims 1-5 of this application conflict with claims 1-6 of Application No. 10/324,240 it should be noted that 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one

application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications such as in different methods of using said composition. See MPEP § 822.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public.

It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and

(d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b) which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the

International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
(1) The name and address of the depository; (2) The name and address of the depositor; (3) The date of deposit;
(4) The identity of the deposit and the accession number given by the depository;
(5) The date of the viability test; (6) The procedures used to obtain a sample if the test is not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:
(1) The accession number for the deposit;
(2) The date of the deposit;
(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
(4) The name and address of the depository.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 are rendered vague and indefinite for the recitation of "per gram dry inert carrier of a bacterial strain" since it is unclear if the carrier is being combined with the bacterial strain or whether the strain itself is dried and intended to function as a carrier in and of itself? It is suggested to change the phrase to –of a bacterial strain per gram of an inert carrier--. Also claim 2 is further rendered vague and indefinite since it is uncertain whether all of the identifying characteristics are intended or just some of

them and if so which ones? Therefore, the metes and bounds of the claims can not be determined. Thus, it is suggested to insert –all of—in between "has" and "the" at line 1 of claim 2.

Claim Rejections - 35 USC § 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticiapted by newly cited Daane et al, note the enclosed PTO-892 Form.

Claim 1 is drawn to a composition comprising about 10^3 cfu (colony forming units) to about 10^{11} cfu per gram dry inert carrier of a bacterial strain that exhibits degradative activity towards a selected toxin such as polyaromatic hydrocarbons.

Daane et al teach about 10^4 cfu (colony forming units) to about 10^9 cfu per gram dry inert carrier of a bacterial strain that exhibits degradative activity towards a selected

toxin such as polyaromatic hydrocarbons. Note the abstract and column 10, lines 20-25 and 40-42. Talc is a dry inert carrier, for example. Also note that the bacteria can be lyophilized, which reads on dried.

The claim is identical to the teachings of Daane et al, and the disclosed strain has the same activity of the claimed strain, and henceforth said disclosed strain inherently possesses all of the same properties as the claimed strain, the claim is considered to be anticipated by the teachings of Daane et al.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being unpatentable over newly cited Komatsu et al.

Claims are discussed above and further drawn to a carrier that comprises porous, ceramic particles having a pore size of from about 0.5 um. Further, the composition comprises about 5% to about 40% growth medium per gram of carrier on a wt/wt dry basis.

Komatsu et al teach a bacterial strain having degradative toxin capability (i.e. decomposition of TCE), see column 3, lines 1-5 and 55-60 and column 4, lines 40-45. The carrier is porous and ceramic, see column 7, lines 23-24 and column 9, line 19. Further, the carrier has pores between 1 um to 50 um, column 7, line 46. Also, at column 7, lines 55-62, the microorganism is introduced into the carrier by immersion of the carrier in a culture medium containing the microorganism. Notably at column 17, lines 10-20 and 42-47, the inoculation of bacteria on the carrier is carried out and the growth medium comprises 10% of the carrier on a dry basis (i.e. 100 ml of culture * 10%

phenol solution = 10% growth medium). At column 12, line 30, the cfu(s) or number of cells is between 10^4 to 10^9 cells/ml of the dry inert carrier.

The claims are identical to the subject matter disclosed by the newly cited Komatsu et al, and are therefore, considered to be anticipated by the teachings therein. The carrier is ceramic and porous as disclosed by Komatsu and hence is a dry inert carrier. There is no difference between the composition of the claims and the disclosed one of Komatsu et al.

Claims 2 is rendered free of the prior art.

All art-rejected claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8200.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah K. Ware

DEBORAH K. WARE
PATENT EXAMINER
Deborah K. Ware
February 14, 2005